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Guidance for Industry: Tobacco Retailer Training Programs

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Guidance for Industry: Tobacco Retail Training Programs

- Guidance represents the Food and Drug Administration's (FDA's) current thinking on tobacco retailer training programs
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Guidance for Industry: Tobacco Retail Training Programs

Draft Guidance for Industry

Tobacco Retailer Training Programs

Draft Guidance

This guidance is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted by September 14, 2010, as described in the notice announcing the availability of the draft guidance in the *Federal Register*. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Tobacco Products (CTP) at 1-877-CTP-1373.

Guidance for Industry

Tobacco Retailer Training Programs

Written comments may be submitted at any time for Agency consideration to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. Alternatively, electronic comments may be submitted to <http://www.regulations.gov>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9:00 a.m. – 4:00 p.m. EDT.

Additional copies are available online at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, 9200 Corporate Blvd., Rockville, MD 20850.



Guidance for Industry: Tobacco Retail Training Programs

Presentation will follow Guidance structure:

- I. Introduction
- II. Background
- III. General Information
- IV. Retailer Training Programs
- V. How Civil Money Penalties Will Be Assessed
For Violations of Regulations



Section I

Introduction



Introduction

Guidance is to assist retailers in implementing training programs for employees to learn about and comply with the Federal laws and regulations restricting:

- Sale and distribution of, including youth access to, cigarettes and smokeless tobacco
- Advertising and promotion of cigarettes and smokeless tobacco



Section II

Background



Background

A. Provisions regarding sale and distribution

Retailers **MUST** comply with the restrictions on sale and distribution of, including youth access to, cigarettes and smokeless tobacco

B. Provisions regarding advertising and promotion

Retailers **MUST** comply with the restrictions on advertising and promotion of cigarettes and smokeless tobacco



Background

C. Civil Money Penalties

- Statute provides for two schedules
- FDA intends to issue regulations establishing standards for approved training programs
- FDA currently using lower schedule
- FDA may consider evidence of a training program during settlement negotiations

D. No-Tobacco-Sale orders

Secretary may impose no-tobacco-sale order on retailers who repeatedly violate restrictions



Section III

General Information



General Information

What products are covered by this guidance?

- Cigarettes
- Cigarette Tobacco
- Smokeless Tobacco



Section IV

Retailer Training Programs



Retailer Training Programs

A. What are the recommended elements to be included in a retailer training program?

1. Applicable Laws and Penalties
2. Health Effects of Youth Tobacco Use
3. Written Company Policies
4. Comprehensive Description of Tobacco Products Covered by Laws Prohibiting the Sale of Tobacco Products to Youth
5. Age Verification Techniques
6. Refusing Sales
7. Testing to Ensure that Employees Have the Knowledge Required



Retailer Training Programs

1. Applicable Laws and Penalties
 - Should describe Federal laws and regulations
 - Should discuss the penalties for violations



Retailer Training Programs

2. Health Effects of Youth Tobacco Use
 - Should include a description of the health and economic effects of tobacco use



Retailer Training Programs

3. Written Company Policies

- Should adopt and enforce a written policy covering Federal laws and regulations
- Should be shared with all employees both verbally and in writing, acknowledged by the employees, and documented in their training records



Retailer Training Programs

4. Comprehensive Description of Tobacco Products Covered by Laws Prohibiting the Sale of Tobacco Products to Youth
 - Should clearly define which tobacco products sold in the retail establishment are subject to the Federal regulations



Retailer Training Programs

5. Age Verification Techniques

- Photographic identification containing a date of birth
- Importance of closely examining photographic identification
- How to verify the authenticity of photographic identification
- Ways to determine whether photographic identification has been altered
- Specific age-verifying techniques
- Insufficient photographic identification



Retailer Training Programs

6. Refusing Sales

- Practical guidance for refusing sales when appropriate
- Right to refuse sales when acting in good faith



Retailer Training Programs

7. Testing to Ensure the Employees Have the Knowledge Required
 - Should require employees to take a written test
 - Should maintain records including, one copy of the test given and a record of the test results for each employees
 - Should retain records for 4 years



Retailer Training Programs

B. What are the recommendations for training frequency, methods, and review

- **Frequency:** Current employees should be trained as soon as practicable, new employees should be trained prior to selling regulated tobacco products, and refreshers should be provided at least yearly and if an employee sells a regulated tobacco product to a person under the age of 18
- **Methods:** May include, but are not limited to: in-store, classroom, written materials, Web or computer-based applications
- **Training Programs Review Following a Violation of the Regulations:** Should review and update training program, as needed, and document any modifications



Retailer Training Programs

C. What hiring and management practices support a retailer training program?

- **Hiring Practices:** Should consider requiring employees who sell regulated tobacco products to be at least 18 years of age
- **Management Practices:** Should consider implementing:
 - Internal compliance check programs
 - Periodic review of in-store videotaping
 - Policies to take employee performance on compliance checks into account
 - Policies to include store's compliance rate in retailer supervisor's performance reviews, if permitted by law



Section V

How Civil Money Penalties Will Be Assessed For Violations Of Regulations



How Civil Money Penalties Will Be Assessed For Violations of Regulations

Retailers are under no obligation to submit their training programs for FDA review, since this is a voluntary program

- Retailer may submit evidence of a training program for purposes of a settlement negotiation when filing an Answer to a Complaint for consideration of further reducing a civil money penalty
- Retailers who have not received a Complaint should NOT submit their training programs



For More Information

Visit:

www.fda.gov/tobacco